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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, BOEHRINGER INGELHEIM INTERNATIONAL GMBH, and BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., Plaintiffs, v. HETERO USA, INC., HETERO LABS LTD. UNIT-III, and HETERO LABS LTD., Defendants.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiffs Boehringer Ingelheim Pharma GmbH & Co. KG, Boehringer Ingelheim International GmbH, and Boehringer Ingelheim Pharmaceuticals, Inc. (collectively, "Boehringer" or "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendants Hetero USA Inc., Hetero Labs Ltd. Unit-III, and Hetero Labs Ltd. (collectively, "Hetero") hereby allege as follows:

THE PARTIES

1. Plaintiff Boehringer Ingelheim Pharma GmbH & Co. KG ("BIPKG") is a limited partnership organized and existing under the laws of Germany, having a principal place of

business at Binger Strasse 173, 55216 Ingelheim, Germany.

2. Plaintiff Boehringer Ingelheim International GmbH ("BII") is a private limited liability company organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

3. Plaintiff Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

4. Upon information and belief, Hetero USA Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1035 Centennial Ave., Piscataway, New Jersey 08854.

5. Upon information and belief, Hetero Labs Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Andhra Pradesh, India.

6. Upon information and belief, Hetero Labs Ltd. Unit-III is a corporation organized and existing under the laws of India, having a principal place of business at 22-110, Industrial Development Area, Jeedimetla, Hyderabad, Telangana, India.

7. Upon information and belief, Hetero USA Inc. is a wholly owned subsidiary of Hetero Labs Ltd., and is an authorized U.S. agent for Hetero Labs Ltd. and Hetero Labs Ltd. Unit-III.

8. Upon information and belief, Hetero Labs Ltd. Unit-III is a division of Hetero Labs Ltd.

NATURE OF THE ACTION

9. This is a civil action concerning United States Patent No. 6,087,380 ("the '380 patent"). This action arises under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

PERSONAL JURISDICTION OVER HETERO

12. Hetero develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this Judicial District.

13. This Court has personal jurisdiction over Hetero because, *inter alia*: (1) Hetero USA Inc. has its principal place of business in this State and is the authorized agent of Hetero Labs Ltd. Unit-III and Hetero Labs Ltd.; (2) Hetero has substantial, continuous, and systematic contacts with this State; (3) Hetero intends to market, sell, and/or distribute its infringing Abbreviated New Drug Application ("ANDA") products ("Hetero's ANDA products," as defined *infra* at paragraph 20) to residents of this State; (4) Hetero maintains a broad distributorship network within this State; and (5) Hetero enjoys substantial income from sales of its generic pharmaceutical products in this State.

14. Hetero USA, Inc. is registered with the State of New Jersey as a drug Wholesaler, under Registration No. 5004050.

15. Additionally, Hetero has routinely consented to this Court's jurisdiction and availed itself of the protections afforded by this Court, including by the filing of counterclaims.

See, e.g., *Takeda GmbH, et al. v. Hetero USA Inc., et al.*, C.A. No. 15-3385, D.I. 12 (FLW)(DEA); *Takeda GmbH, et al. v. Hetero USA Inc., et al.*, C.A. No. 16-1280, D.I. 8 (FLW)(DEA).

16. Alternatively, to the extent the above facts do not establish personal jurisdiction over Hetero Labs Ltd. Unit-III or Hetero Labs Ltd., this Court may exercise jurisdiction over these Defendants pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Hetero Labs Ltd. Unit-III and Hetero Labs Ltd. would be foreign defendants not subject to personal jurisdiction in the courts of any state; and (c) Hetero Labs Ltd. Unit-III and Hetero Labs Ltd. have sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Hetero Labs Ltd. Unit-III and Hetero Labs Ltd. satisfies due process.

PATENT-IN-SUIT

17. BIPI is the holder of New Drug Application ("NDA") No. 22-512, by which the United States Food and Drug Administration ("FDA") first granted approval for 75 mg and 150 mg dabigatran etexilate mesylate capsules. The dabigatran etexilate mesylate capsules described in BIPI's NDA are prescribed, *inter alia*, to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. Boehringer sells these capsules in the United States under the trade name "PRADAXA®."

18. BIPKG owns the '380 patent, which was duly and legally issued on July 11, 2000, and is titled "Disubstituted Bicyclic Heterocycles, the Preparations and the Use Thereof as Pharmaceutical Compositions." BII and BIPI have an exclusive license under the '380 patent in the United States from BIPKG. A copy of the '380 patent is attached as Exhibit A.

ACTS GIVING RISE TO THIS ACTION

COUNT I – INFRINGEMENT OF THE '380 PATENT BY HETERO

19. Plaintiffs reallege paragraphs 1-18 as if fully set forth herein.

20. Defendant Hetero filed with the FDA ANDA No. 207961 seeking approval to engage in the manufacture, use, sale, offer for sale, and/or importation of 75 mg and 150 mg dabigatran etexilate mesylate capsules ("Hetero's ANDA products").

21. On or about December 5, 2014, Hetero sent a letter to Plaintiffs that included Hetero's representation that it had filed ANDA No. 207961 ("Hetero's First Notice Letter"). Hetero's First Notice Letter did not include a certification that the '380 patent was invalid, unenforceable, and/or not infringed.

22. As of December 5, 2014, ANDA No. 207961 included a certification with respect to the '380 patent under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(III). As of December 5, 2014, Hetero was not seeking approval from the FDA of its ANDA prior to the expiration of the '380 patent.

23. As of December 5, 2014, Hetero had not received an opinion that the '380 patent was invalid, unenforceable, and/or not infringed.

24. As of December 5, 2014, Hetero was unaware of factual and legal bases for contending that every claim of the '380 patent was invalid, unenforceable, and/or not infringed.

25. On or about April 18, 2016, Hetero sent a second letter ("Hetero's Second Notice Letter") to Plaintiffs in which Hetero represented that its ANDA No. 207961 included a certification with respect to the '380 patent under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), and that Hetero was seeking approval of its ANDA prior to the expiration of that patent.

26. Hetero's Second Notice Letter does not deny infringement of claim 9 of the '380 patent separate and apart from a defense of patent invalidity.

27. The only patent invalidity defense asserted in Hetero's Second Notice Letter with respect to the '380 patent is a defense of obviousness under 35 U.S.C. § 103.

28. This action was commenced within 45 days of the receipt of Hetero's Second Notice Letter.

29. Because Hetero seeks approval of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of a drug claimed in the '380 patent, and a drug the use of which is claimed in the '380 patent, before its expiration, Hetero has infringed the '380 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

30. Plaintiffs are entitled to a declaration that, if Hetero commercially manufactures, uses, sells, offers to sell, and/or imports any of Hetero's ANDA products, or induces or contributes to any such conduct, it would further infringe the '380 patent pursuant to 35 U.S.C. § 271(a), (b), and/or (c).

31. The commercial manufacture, use, sale, offer for sale, and/or importation of Hetero's ANDA products, if approved by the FDA, prior to the expiration of the '380 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of the '380 patent. Hetero is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of Hetero's ANDA No. 207961 be a date that is not earlier than the expiration date of the '380 patent, or any later expiration of exclusivity for the '380 patent to which Boehringer is or may become entitled.

32. Upon information and belief, Hetero was aware of the existence of the '380 patent, and was aware that the filing of its ANDA and certification with respect to the '380

patent constituted an act of infringement of that patent.

33. Hetero's statement of the factual and legal bases for its opinion regarding the noninfringement and invalidity of the '380 patent contained in Hetero's Second Notice Letter is devoid of any objective good-faith basis in either the facts or the law.

34. Plaintiffs will be irreparably harmed by Hetero's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment be entered that Defendant Hetero has infringed the '380 patent by submitting Hetero's ANDA No. 207961;

B. A Judgment be entered that this case is exceptional, and that Plaintiffs are entitled to their reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

C. A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendant Hetero, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the drugs or methods of administering drugs claimed in the '380 patent, including any exclusivities or extensions;

D. An Order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Hetero's ANDA No. 207961 be a date that is not earlier than the expiration date of the '380 patent, or any later expiration of exclusivity of the '380 patent to which Plaintiffs are or may become entitled; and

E. Such other and further relief as the Court may deem just and proper.

Dated: April 26, 2016

By: s/ Charles M. Lizza

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

I hereby certify that the matter captioned *Boehringer Ingelheim Pharma GmbH & Co. KG, et al. v. Teva Pharms. USA, Inc., et al.*, Civil Action Nos. 14-7811, 15-1662, and 15-7880 (MLC)(TJB) (Consolidated) is related to the matter in controversy because the matter in controversy involves the same plaintiffs and the same patent.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: April 26, 2016

By: s/ Charles M. Lizza

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